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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

1 RECORD OF ORAL HEARING  
2  
3 U.S. PATENT AND TRADEMARK OFFICE  
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5  
6 BEFORE THE PATENT TRIAL AND APPEAL BOARD  
7

8  
9 *Ex parte* BEKA SOLOMON  
10

11  
12 Appeal 2012-002100 & 2012-004898  
13 Application 11/358,951 & 09/441,140  
14 Technology Center 1600  
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16  
17 Oral Hearing Held: July 24, 2012  
18

19  
20 Before DONALD E. ADAMS, DEMETRA J. MILLS, and  
21 JEFFREY N. FREDMAN, *Administrative Patent Judges*.  
22

23 APPEARANCES:

24  
25 ON BEHALF OF THE APPELLANT:

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32 The above-entitled matter came on for hearing on Tuesday, July  
33 24, 2012, commencing at 9:00 a.m., at the U.S. Patent and Trademark

1 Office, 600 Dulany Street, Alexandria, Virginia, before a Notary  
2 Public.

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4

P R O C E E D I N G S

5 USHER: Calendar Number 7, Appeal Number 2012-  
6 2100, Mr. Browdy.

7 MR. BROWDY: Thank you.

8 JUDGE ADAMS: Good morning, Mr. Browdy.

9 MR. BROWDY: Good morning.

10 JUDGE ADAMS: How are you?

11 MR. BROWDY: Good.

12 JUDGE ADAMS: All right. We're familiar with your record.  
13 You're going to handle both of these cases together?

14 MR. BROWDY: Yes. And if it pleases the court, I would like  
15 to kind of intermix and intertwine and not go in order one case and  
16 then the other because the issues are so --

17 JUDGE ADAMS: Okay. I don't know what that's going to do  
18 with our transcript, but we'll work it out.

19 MR. BROWDY: Okay. Ah well.

20 JUDGE ADAMS: That's fine.

21 MR. BROWDY: Same transcript for both cases, I would  
22 suggest.

1 JUDGE ADAMS: Okay.

2 MR. BROWDY: This is Shulamit Hirsh, is the head of the  
3 patent department at RAMOT at Tel Aviv University, which is the  
4 licensed [unintelligible] of this case. They're the licensing arm of Tel  
5 Aviv University.

6 So, the present invention relates to the discovery that antibodies  
7 can be directed to a certain place on a aggregating protein that will  
8 prevent the aggregation of that protein. Call it a chaperone in our  
9 specification. It will -- or it will, when binds to the plaque or the  
10 aggregated protein that's already formed, it will cause it to  
11 disaggregate. The discovery that such antibodies exist that can  
12 actually bind to a place on the protein that will prevent its aggregation  
13 is the basis of the invention. Turns out that some of the antibodies  
14 that we found worked for this purpose are known antibodies. In fact,  
15 our specification uses antibodies that we bought that were preexisting  
16 antibodies, and we discovered that among the antibodies that were  
17 tested was one that worked and establishing proof of concept. The  
18 specification explains how you can raise antibodies against a beta,  
19 particularly 1 to 28 is the one that they found would work, which is  
20 several [unintelligible] doses that brought piece of the protein, and  
21 screen for those that bind to a beta, and screen of those for the ones  
22 that will prevent aggregation or cause disaggregation.

1 JUDGE ADAMS: So, how does your specification get us to an  
2 antibody that binds to an extent at least as great --

3 MR. BROWDY: I'm sorry?

4 JUDGE ADAMS: How do we get from your specification to  
5 an antibody that binds to an extent at least as great or gives results or  
6 inhibits aggregation to an extent at least as great as that obtainable  
7 with antibody AMY33 [spelled phonetically], the subject of the  
8 examiner, I believe, his written description rejections.

9 MR. BROWDY: That's correct. In my answer to that question,  
10 may I put up this --

11 JUDGE ADAMS: Oh, please.

12 MR. BROWDY: -- demo to demonstrate --

13 JUDGE ADAMS: We have the easel all set up for you, so.

14 MR. BROWDY: Have the easel, might as well use it.

15 JUDGE ADAMS: Exactly.

16 MR. BROWDY: [unintelligible] excuse me. This is just to  
17 help to understand the rejections and the way the claims are worded in  
18 how the -- how they relate to the various claims. So, there's two  
19 columns going up and down, and there's two rows going across. The  
20 two columns, A and B, are the claims that have -- that the antibody --  
21 defines the antibody as binding A beta and inhibiting aggregation of A  
22 beta or maintain the solubility of soluble A beta to extent at least as

1 great as that obtainable with AMY33. That's the -- those claims there  
2 are directed to your question. The B claims, you can see below I have  
3 listed the -- only the independent claims. So, 219, 222, and 224 in the  
4 first reissue, and Claim 17 in the second reissue, and then the same --  
5 those claims below, those are just binds A beta and disaggregates an  
6 aggregated A beta. Those claims do not have that language about at  
7 least as great as that obtainable with AMY33. Those are only on the  
8 inhibiting aggregation claims.

9 And then on the I -- and II on the left -- we have a set of claims  
10 obtainable, the antibodies obtainable using an immunogen consisting  
11 of a peptide, consisting of residues 1 through 28 of A beta. The other  
12 set of claims says that the antibody recognizes an epitope within  
13 residues 1 to 28 of A beta, avoiding the obtainable language. No  
14 objection to written description for there. And, so, these are -- so we  
15 have four sets of claims, four sets of independent claims. I just  
16 wanted you to understand how those independent claims relate to the -  
17 -

18 JUDGE ADAMS: Written description.

19 MR. BROWDY: -- relate to these four features. So, if you'll  
20 look down at B2 in the lower right hand corner, these are the claims --  
21 Claim 225, 228, and 35 of the divisional, these are the claims that bind  
22 A beta and disaggregate an aggregate of A beta, and the -- recognizes

1 an Epitope within residues 1 through 28 of A beta. Those claims, in  
2 the first divisional -- first reissue, have only one rejection, 225 has  
3 only one rejection, the prior art rejection of Walker. And, in fact, 228  
4 has no rejection.

5 JUDGE ADAMS: Okay. Without walking us through all the  
6 different rejections, let's just talk about Column A there, and tell me  
7 back to my original question where we have written description to  
8 that. Thank you, though.

9 MR. BROWDY: It's not new matter, but it's not -- it's new  
10 matter and a written description.

11 JUDGE ADAMS: They're kind of tied together.

12 MR. BROWDY: The new matter rejection. It's not new matter  
13 because the -- because as long as the specification inherently or  
14 implicitly supports the language of the claim, then that's considered to  
15 not be a new matter, according to the written description guidelines. I  
16 believe that the -- that this concept of the AMY33 and above is  
17 inherently or inherently or explicitly disclosed in the specification as  
18 filed, because in the specification as filed, before we put in that  
19 statement that's higher than obtainable with AMY33, we covered  
20 every degree of inhibition of aggregation from just above negligible to  
21 total inhibition, all right? Now, within that range, we had two  
22 examples. We had the 6F3D [spelled phonetically] antibody, which

1 was lousy and just a teeny bit of inhibition, and we had the AMY33  
2 that had good inhibition, but it wasn't 100 percent inhibition, all right?

3 So, effectively, we started off with a range, going just above  
4 negligible to the highest you could possibly have, and we had a point  
5 in that range, which was AMY33.

6 JUDGE FREDMAN: Where's the range discussed in the spec?

7 MR. BROWDY: Where is it discussed in the spec?

8 JUDGE FREDMAN: Yeah.

9 MR. BROWDY: It's -- the range -- it's not discussed, it's not  
10 determed [sic] a range in the spec. The spec supported by the claims  
11 is originally filed, and we objected to a new matter or written  
12 description, which said that I'm claiming any antibody that inhibits  
13 aggregation, and I had the two examples, one of which I said was so  
14 little aggregation that that's not part of the invention, and the other one  
15 was AMY33.

16 So, we have -- and if you look at the spec --

17 JUDGE FREDMAN: I mean, because, essentially, Ariad just  
18 told us that what's obvious is not necessarily described, right?

19 MR. BROWDY: That's correct.

20 JUDGE FREDMAN: So, it may be obvious that the range  
21 should be higher than the AMY33, but I'm not sure that it's totally  
22 described that you want a range higher than AMY33.



1 MR. BROWDY: Yeah. There's no question that -- I'm not  
2 taking the position that just because it's obvious it's -- you've gotten a  
3 description. I'm taking the position that -- I mean, there are range  
4 cases, which I cited in the brief -- I think it's a little bit of stressed talk  
5 about those range cases, but --

6 JUDGE FREDMAN: They're not clear.

7 MR. BROWDY: -- they are examples that if you have a certain  
8 range, you have a point within the range, and you have a new  
9 description from that point to the rest of the range. So, although I  
10 don't have a 35 to 65, I have a 2 to 100, and then I have something in  
11 the middle, maybe 70. And, so, I'm saying 70 to 100 is implicitly  
12 disclosed.

13 JUDGE ADAMS: But here we're talking about antibodies.

14 MR. BROWDY: Yes, sir.

15 JUDGE ADAMS: And you have a disclosure of an antibody  
16 AMY33. It's not absolute, but it's sort of in the topper tier, the upper  
17 tier, right? And now you're talking about --

18 MR. BROWDY: No, it's not, it's not --

19 JUDGE ADAMS: Okay.

20 MR. BROWDY: Between you and me -- [inaudible].

21 JUDGE ADAMS: Now we're talking about something from  
22 AMY33 and above, and we're talking about antibodies. So, where

1 have you described those antibodies?

2 MR. BROWDY: Because we describe it that you --

3 JUDGE ADAMS: I mean, for all I know --

4 MR. BROWDY: -- [unintelligible] or you can raise an antibody

5 --

6 JUDGE ADAMS: For all I know, I'll never ever get any  
7 antibody better than or even the same as AMY33. That might be the  
8 best that you can ever get. That's like the magic bullet antibody, as far  
9 as I know, from your disclosure, unless you can tell me otherwise.

10 JUDGE FREDMAN: This is a straight description issue we're  
11 talking about, and not the new matter.

12 MR. BROWDY: Okay. On the written description, I think that  
13 -- I feel much more comfortable. The -- and, in fact, I found a very  
14 recent board decision, non-precedential, but I think that it's instructive,  
15 and it is *ex parte* Gately, G-A-T-E-L-Y, Appeal Number 2011-  
16 003784, Application number 10-267565. APJs Scheiner, Prats, and  
17 Walsh [spelled phonetically]. And here's a claim where they had --  
18 where the claim was to an antibody, an isolated monoclonal antibody,  
19 which binds with a 40KDA KLMF [spelled phonetically], just like our  
20 binds say A beta, wherein said [unintelligible] antibody is capable of  
21 blocking CLMF-induced proliferation of lymphocytes of a particular  
22 cell. And the specification showed antibodies to the 40KDA subunit

1 of CLMF, some of which had the property of blocking induced  
2 proliferation, and some of which didn't. And it was a written  
3 description rejection.

4 JUDGE FREDMAN: But how many species were there that  
5 actually worked?

6 MR. BROWDY: Three.

7 JUDGE FREDMAN: Okay. So, there were more.

8 MR. BROWDY: Yeah. There were more than one.

9 JUDGE FREDMAN: Okay.

10 MR. BROWDY: But --

11 JUDGE FREDMAN: Because one and more than one is --

12 MR. BROWDY: [inaudible] actually worked it in where he  
13 wants. It was zero.

14 JUDGE FREDMAN: But that was [unintelligible]. Wands  
15 [spelled phonetically] is an enablement case, not description.

16 MR. BROWDY: That's true. The --

17 JUDGE FREDMAN: We're not arguing the enablement -- the  
18 examiner didn't even make an enablement rejection here, reasonably  
19 [unintelligible].

20 MR. BROWDY: Right. But they found it very significant here  
21 that Wands [spelled phonetically] says that one uses a screen. You  
22 don't need to have a description of CDRs [spelled phonetically] with

1 the antibody or structure, this and that. You can [unintelligible].

2 JUDGE FREDMAN: We're not really challenging enablement.  
3 This is a description.

4 MR. BROWDY: No. This is a written description.

5 JUDGE FREDMAN: No, I understand, but they have more  
6 species, so they had -- they knew that you could make more.

7 MR. BROWDY: But the written description guidelines have  
8 lots of examples where there's like one species which claim 95 percent  
9 or more, and you have -- all you have is the [unintelligible] --

10 JUDGE ADAMS: Let me just --

11 MR. BROWDY: -- where one is sufficient to satisfy the --

12 JUDGE ADAMS: Let me just cut through that case and say it's  
13 non-precedential and the facts are different, all right?

14 So, getting to your case, what is it in your specification that  
15 supports that range, or an antibody, or discloses an antibody that's  
16 AMY33, at least as good as or better?

17 MR. BROWDY: Because my specification says that you take a  
18 hybrid [unintelligible], you raise them against A beta, and you stream,  
19 and you disclose the assay that determines the amount of inhibition.

20 JUDGE ADAMS: So, what's the expectation that I'll ever get --

21 MR. BROWDY: [inaudible] past comparison, comparative  
22 assay --

1 JUDGE ADAMS: So, this gets back to my magic bullet.  
2 AMY33 is the best you'll ever get. Where's the disclosure in the  
3 specification that suggests to anyone that you might get better, and  
4 describe that antibody?

5 MR. BROWDY: Number one, there's no reason to believe that  
6 because an antibody technology, you always find a range of activity  
7 from near hybrid [unintelligible]. And to believe that the one that we  
8 happened to mention, that there's impossible to get anything higher, is,  
9 number one, is a stretch, and number two, and if it were true, you  
10 know, so be it. Then all I can claim is AMY33, and nobody's ever  
11 going to infringe with anything higher.

12 JUDGE ADAMS: Okay.

13 MR. BROWDY: And that doesn't mean that there's lack of  
14 written description.

15 JUDGE ADAMS: So, I think what you're saying is other than  
16 generic hydromomic [spelled phonetically] technology, there's no other  
17 disclosure of any antibody that has the activity of your claim?

18 MR. BROWDY: There's no other --

19 JUDGE ADAMS: Specific disclosure of any antibody that  
20 meets the requirement of your claim?

21 MR. BROWDY: No, sir.

22 JUDGE ADAMS: Okay. So, do we want to talk about the

1 prior art?

2 MR. BROWDY: Sure.

3 JUDGE ADAMS: Okay. And I -- just as you're -- as we're  
4 segueing, what is it that you mean by genetically engineered antibody  
5 in, for example, Claim 210 of the 4898 appeal?

6 MR. BROWDY: Right. This --

7 JUDGE FREDMAN: Is that the [unintelligible]?

8 JUDGE ADAMS: is it just a process --

9 MR. BROWDY: Yes, it's the [unintelligible].

10 JUDGE ADAMS: Is it just a process limitation of this  
11 composition?

12 MR. BROWDY: The -- it is a -- there's a reference at -- if you  
13 look at Column 6, Lines 7 to 14, it talks about a method of treating a  
14 protein aggregation disease with [unintelligible] steps of preparing  
15 citing this Haber [spelled phonetically] paper, or selecting an  
16 antiaggregation molecule, such as the monoclonal antibody,  
17 genetically engineered monoclonal antibody fragment, or peptide.  
18 The Haber paper goes into great detail about how to make genetically  
19 engineered monoclonal antibodies, such as single chain antibody,  
20 humanized antibody, that type of thing. But, the claim specifies that  
21 you have to start with an antibody that has some properties. You can  
22 genetically engineer it in whatever way that you want to, and it must

1 retain the properties when you finish. So, that's all in the claim. And  
2 the --

3 JUDGE FREDMAN: See, the problem here for me, and -- is  
4 that if I treat genetically engineered as a product by process limitation,  
5 right? So, I say that, well, all that really means is we've done  
6 something to obtain an antibody somehow, right? And I say it  
7 [unintelligible] AMY33, right, and I look at Walker, and Walker's got  
8 this 10D5 fragment, right? So, he's got an FAB [spelled phonetically]  
9 fragment of 10D5. Well, that 10D5 fragment, we know from the  
10 [unintelligible] art essentially inherently is better than AMY33, so it  
11 meets that requirement. It's, I mean it could have been obtained by  
12 genetically engineering it, I suppose. It -- you could certainly create  
13 an expression vector and express 10D5, and it, you know, all the  
14 functional limitations it's going to meet. So, why is that Walker not  
15 sort of made -- rendered this obvious?

16 MR. BROWDY: Because the -- because, number one, it --  
17 Walker does not teach -- the only therapeutic use that Walker teaches  
18 --

19 JUDGE FREDMAN: No, no. But this is for the product  
20 claims, not the method claims.

21 MR. BROWDY: Okay. But, the product claim, the --

22 JUDGE FREDMAN: Therapeutic is intended use. That's not --

1 MR. BROWDY: Yeah.

2 JUDGE FREDMAN: Okay.

3 MR. BROWDY: We don't -- okay. We don't have an  
4 anticipation. We have an obviousness rejection.

5 JUDGE FREDMAN: But the anticipation is the epitome of --

6 MR. BROWDY: [unintelligible] modification case of  
7 obviousness, we are going to get results that are totally unexpected  
8 and will blow you out of the water. Because, if you use this antibody  
9 of Walker in the way that Walker says you use it, you're going to get -  
10 - you have one expectation, and when you discover that this antibody  
11 causes disaggregation of the plaque, you're going to be shocked. This  
12 is unexpected results because we've discovered a property of this  
13 antibody. Walker teaches -- and it's a property. This aggregates  
14 plaque.

15 JUDGE ADAMS: Okay. Let's move --

16 MR. BROWDY: And so therefore the --

17 JUDGE ADAMS: Let's move back to the composition.

18 MR. BROWDY: I'm sorry?

19 JUDGE ADAMS: We're talking about the method claims.  
20 Let's talk about the composition claims.

21 MR. BROWDY: No. I'm talking about Inray of --

22 JUDGE ADAMS: No? No?



1 MR. BROWDY: Case it says that chemical compounds and  
2 properties are all together when you're determining the obviousness of  
3 a chemical compound, and our antibody, this composition, the  
4 antibody use in our composition has certain properties, and some of  
5 those properties are unexpected [unintelligible] unexpected.

6 JUDGE ADAMS: Well, Walker has an antibody that has those  
7 same properties?

8 MR. BROWDY: Huh? Nobody knew it had those properties.

9 JUDGE ADAMS: It's implicit. You just told me there's case  
10 law that supports a compound and its properties all go together, right?

11 JUDGE FREDMAN: They're inseparable.

12 MR. BROWDY: The case law --

13 JUDGE ADAMS: They're inseparable.

14 MR. BROWDY: The case law says Inray --

15 JUDGE ADAMS: Package?

16 MR. BROWDY: -- May says that this thing has properties In re  
17 May [spelled phonetically]. You had an adjacent homologue, and  
18 both the anticipated compound and the prima facie obvious compound  
19 were known to be analgesics. They discovered not only is it  
20 analgesic, but they are non-addictive, and it was determined that this  
21 property of non-addictive on the homologue -- which, by the way, was  
22 also unknown but possessed by the main compound -- is sufficient to

1 establish unexpected results and rebut a *prima facie* case of  
2 obviousness for the adjacent homologue. And May says you have a  
3 test of laying the important -- you have --

4 JUDGE FREDMAN: Well, what if we say it's anticipated, and  
5 this is the problem -- this is the problem. The concern is really that it's  
6 anticipated, not that it's obvious.

7 MR. BROWDY: There's no anticipation --

8 JUDGE FREDMAN: I know it's not made, but that's our  
9 concern.

10 MR. BROWDY: We don't have no --

11 JUDGE FREDMAN: I understand that. We can -- there's  
12 4150B that we could do it new grounds.

13 MR. BROWDY: How is there -- you admitted that there's no  
14 genetic engineering. You said it could be.

15 JUDGE FREDMAN: No, no. I said that's product by process,  
16 but if I treat it as a product by process limitation, then the Walker and  
17 the fragment meets the claim.

18 Okay. We can move on. That's not a rejection-related issue  
19 now.

20 MR. BROWDY: Okay.

21 JUDGE ADAMS: You were talking about the weighing of  
22 evidence with regard to In re May.

1           MR. BROWDY: Yeah. And that -- if there is a reason to make  
2 a change, and then there is something unexpected you find and you  
3 make that change, then you waive the relative importance of the -- of  
4 your disclosed reason for making the change with the reason that  
5 you've discovered. And, of the more important one, i.e. in May, the  
6 fact that --

7           JUDGE ADAMS: So, that would be a change between one  
8 homologue to its adjacent homologue, right?

9           MR. BROWDY: That's expect -- you would expect that it  
10 would have the analgesic property of the main compound.

11          JUDGE ADAMS: Okay.

12          MR. BROWDY: [unintelligible] not addictiveness outweigh  
13 that expected result.

14          JUDGE ADAMS: And here I am, an antibody taught by the  
15 prior art that, for all extensive purposes, meets the limitation of your  
16 claim. It just doesn't say that it has any effect on aggregation.

17          MR. BROWDY: Right. And the compound claim in Inray  
18 May didn't say anything about it being non-addictive. That's a  
19 compound claim. Now, the property and the compound are all part of  
20 the same thing.

21          JUDGE FREDMAN: Now this already would apply it as well  
22 to the combination of Walker and, say, Becker [spelled phonetically],

1 which is probably the best, 103, over the method claims, I mean.

2 MR. BROWDY: Becker, you know, Roy Becker, Becker says  
3 use an antibody that's specific to the beta sheet form of the amyloid,  
4 and D5 isn't specific to the intent to that, and D5 binds to the, to both  
5 forms. It is not an antibody of Becker. How does Becker and Walker  
6 together make it obvious to -- that Walker is going to have therapeutic  
7 properties, specifically?

8 JUDGE FREDMAN: Or just aggregation or prevention of  
9 aggregation properties.

10 MR. BROWDY: Yeah.

11 JUDGE FREDMAN: Okay.

12 MR. BROWDY: There's no suggestion of that, because it's not  
13 an antibody of Becker. Becker doesn't have any antibodies. Becker's  
14 not enabling. But, aside from that, what it does teach is that you  
15 would like to find an antibody that's specific to the beta sheet and  
16 doesn't bind to the other one, and yet 10D5 finds both, and AMY33,  
17 which is the Fickle [spelled phonetically] reference, also binds to non-  
18 aggregated. It binds to the [unintelligible] form. So, it's -- neither of  
19 those are antibodies of Becker. Becker doesn't really add anything.

20 JUDGE FREDMAN: Right.

21 JUDGE ADAMS: Anything else you want to say about the  
22 prior art rejection?

1 MR. BROWDY: Yes. Let me just see. Let me -- we talked  
2 about Becker. We talked about Walker. We talked a little bit about  
3 Fickle. I think that -- unless you have any other question on the prior  
4 art --

5 JUDGE ADAMS: We're done with the prior art.

6 JUDGE MILLS: I have one more question regarding Walker.  
7 Why would the principles of In re Best [spelled phonetically] not  
8 apply to the Walker antibody, and why is it not now appellant's  
9 burden to show that it doesn't have the disaggregating properties?

10 MR. BROWDY: Okay. You're going to have to help me out  
11 with the Inray Best --

12 JUDGE MILLS: Best says that the patent office doesn't  
13 have the ability to test the antibodies, and if the examiner shows that  
14 the antibodies or the same or substantially the same, it's now  
15 appellant's burden to show that they --

16 JUDGE ADAMS: Inherency argument.

17 MR. BROWDY: Yeah.

18 JUDGE MILLS: Yeah.

19 JUDGE ADAMS: Inherency argument.

20 MR. BROWDY: The patent office has to have some reason to  
21 make us go through this task. I mean, Marziachi [spelled  
22 phonetically], you have to -- the examiner has the burden to show

1 reasons why it would be expected, or you -- that even that it's  
2 possible, it would be reasonable to assume that it's going to have these  
3 properties, and that end, you'd shift the burden to me to show it  
4 doesn't have those properties. All that Walker says is that it binds to  
5 plaque, and it's unreasonable to say that anything that binds the plaque  
6 would be expected to disaggregate the plaque. That's just not -- that's  
7 -- we discovered specific antibodies that do. More recent information  
8 that we have provided you in this table that there are a lot of  
9 antibodies that bind to plaque that don't disaggregate it. If it would be  
10 expected that binding the plaque across disaggregation of the plaque,  
11 you don't think that Walker would have said, "I found something that  
12 bound to plaque! I can cure Alzheimer's disease!" No, he didn't say  
13 that because that's not -- that wasn't expected at the time of the present  
14 invention. All that he'd expect is that it binds.

15 So, I don't think that the Patent Office has provided enough of a  
16 reason to expect that the 10D5 antibody of Walker without knowledge  
17 of any of the post filing date publications would be expected to  
18 disaggregate -- prevent aggregation.

19 JUDGE MILLS: Okay. Very good. Thank you.

20 JUDGE ADAMS: I think we concluded that we're done with  
21 the prior art issue.

22 JUDGE MILLS: Yeah.

1 JUDGE ADAMS: We're done with the new matter and written  
2 description, so that pretty much takes care of the 4898 case as far as I  
3 understand, is that right?

4 MR. BROWDY: That's correct.

5 JUDGE ADAMS: So now we have one remaining issue left in  
6 the 2100 case.

7 MR. BROWDY: Right.

8 JUDGE ADAMS: Go.

9 MR. BROWDY: I wanted to -- most of the briefing went to the  
10 question of Orita [spelled phonetically] and Doyle [spelled  
11 phonetically], and what kind of changes to the claims are sufficient to  
12 take it out of the Orita situation.

13 JUDGE FREDMAN: So, let me just set the background on  
14 that. It looks like the way it's set up, the original restriction had three  
15 grips -- the method of screening, and two treatment methods. And  
16 then you elected and you elected the method of screening, at which  
17 point the prosecution continued, and I guess eventually went on. And  
18 then you filed the reissue, then you filed a very broad claim for  
19 treating, which then the examiner restricted again, essentially into a  
20 very narrow claim for treating. But in all -- in either case, they were  
21 both treating methods that would have fallen into groups two, three, or  
22 maybe four if we created. Who knows what the original examiner

1 would have done.

2 MR. BROWDY: Only group four [unintelligible] examiner --

3 JUDGE FREDMAN: No, no -- I want to make it --

4 MR. BROWDY: Claim 24.

5 JUDGE FREDMAN: No, no, no. I know the examiner pointed  
6 to Claim 24, but even if we said it fell a degree of two, which would  
7 be 7 through 23 or something, I think, it still would have been a  
8 treating claim. Those two groups are both treating groups. They're  
9 different kinds of treatment. One had the vector and all that business.  
10 But --

11 MR. BROWDY: Different kind of treatments, or different  
12 matches?

13 JUDGE FREDMAN: Yeah, yeah, right. But, so, your new  
14 claims all fall into one of the other two groups, not into group one, the  
15 elected group. Is that fair, or am I --

16 MR. BROWDY: Let's --

17 JUDGE FREDMAN: Because Doyle's a pretty good situation  
18 where the --

19 MR. BROWDY: I disagree, but to let me follow your thought,  
20 let's concede it. I think that indeed when the examiner said that every  
21 single species is patent and distinct from every other one, then I think  
22 that my species that I find the elect is also patently distinct from the



1 genus. But, I want to go and follow the rest of your thoughts.

2 JUDGE FREDMAN: Okay.

3 MR. BROWDY: Let's take the position that is the same  
4 invention. Is that sufficient under Orita, and under case in the last  
5 year at the federal circuit, it confirms what Doyle says that the issue is  
6 not is it the same invention, would it have been restricted if it had  
7 been presented? The issue is are the claims substantially the same?  
8 Because Doyle says that the -- that 251 is broadly applicable, and that  
9 Orita carved out something from the broad applicability of 251, which  
10 is supposed to be remedial and generously interpreted. 251 and --  
11 Orita created an exception for claims that are substantially identical to  
12 the claims that you had, and you could have filed -- that you could  
13 have filed [unintelligible] but you didn't. And Doyle agrees and said  
14 that these claims were not substantially identical to previously non-  
15 elected claims, and therefore 251 applies, but the Orita doctrine  
16 doesn't. And the examiner quibbled about, "Oh, well, there was two  
17 grounds in Doyle, and so therefore this was dicta." Well, here's  
18 another case, April 23, 2012, from the federal circuit. It's Landmark  
19 Streams L.L.C. [spelled phonetically] versus Morgan Lewis and  
20 Bockius L.L.P. [spelled phonetically]. 676F3rd 1354 [spelled  
21 phonetically], 102 USPQ second.

22 JUDGE FREDMAN: Can you read the number again, 676F

1 third -- what's the last?

2 MR. BROWDY: 676F third, 1354.

3 JUDGE FREDMAN: Thank you.

4 MR. BROWDY: We don't use the PQ anymore.

5 JUDGE FREDMAN: All right.

6 MR. BROWDY: In this case, they filed it -- they had a  
7 restriction requirement with the original prosecution, and they filed a  
8 divisional, but they screwed up and they left out drawings and pages,  
9 and by the time they fixed it, a year had passed from the publications,  
10 so they couldn't prosecute the divisional. So, they filed claims in the  
11 reissue, and the -- and this kind of a malpractice case, but that's  
12 another issue. The federal circuit said, "Our precedent provides that  
13 the reissue statute may not be used to grant patent protection for  
14 substantially identical claims that were not properly prosecuted in  
15 original applications. Our precedent --" citing in *Orita* -- "Our  
16 precedent also recognizes that the reissue statute is properly invoked  
17 when the new claims in the reissue application are not substantially  
18 identical to previously non-elected claims, *In re Doyle*," excepting  
19 what I consider to be a valid holding of *In re Doyle*. And then they  
20 said that the landmark reissue application did not present substantially  
21 identical claims to the claims of the failed 916 divisional application  
22 and consequently satisfied the requirements of section 251. It was

1 clearly the same invention, except it had a very different scope. And  
2 that's what we have. And In re Orita doesn't apply.

3 JUDGE ADAMS: That's all you got?

4 MR. BROWDY: That's my story, and I'm sticking to it.

5 JUDGE ADAMS: All right. Any questions?

6 JUDGE MILLS: No questions.

7 JUDGE ADAMS: Questions?

8 JUDGE FREDMAN: No more.

9 JUDGE ADAMS: Anything else for you?

10 MR. BROWDY: Thank you very much.

11 JUDGE ADAMS: Pleasure.

12 (Whereupon, the proceedings at 9:55 a.m. were concluded.)